CLAIMS

We claim:

1. A method for evaluating the HbA_{1c} of a patient based on BG data collected over a first predetermined duration, said method comprising:

preparing the data for estimating HbA_{1c} using a predetermined sequence of mathematical formulas defined as:

pre-processing of the data;

estimating HbA_{1c} using at least one of four predetermined formulas; and

validation of the estimate via sample selection criteria.

2. The method of claim 1, wherein said first predetermined duration is about 60 days.

3. The method of claim 1, wherein said first predetermined duration ranges from about 45 days to about 75 days.

4. The method of claim 1, wherein said first predetermined duration ranges from about 45 days to about 90 days.

5. The method of claim 1, wherein the preprocessing of the data for each patient comprise:

conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

6. The method of claim 1, wherein the preprocessing of the data for each patient using predetermined mathematical formulas defined as:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l) via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals ,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

7. The method of claim 6, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

8. The method of claim 6, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

9. The method of claim 8, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

10. The method of claim 9, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is ≤about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

11. The method of claim 10 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said method comprising:

estimating HbA_{1c} using at least one of four predetermined mathematical formulas defined as:

a) HbA1c = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 6.

RLO1 is the Low BG Index of claim 6.

RHI1 is the High BG Index of claim 6; or

c) HbA1c = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA1c reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 6; or

d) HbA1c = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 6.

12. The method of claim 11, wherein said second predetermined duration is about three months.

13. The method of claim 11, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

14. The method of claim 11, wherein said second predetermined duration ranges from about 2.5 months to six months.

15. The method of claim 11, wherein the validation of the HbA1c estimate using sample selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 6

RHI1 is the High BG Index of claim 6; or

d) a randomness of data criterion-2 wherein HbA1c estimate is validated or displayed only if the ratio (NO6 >= about 3%).

wherein

N06 is the percentage of readings during the night of claim 6.

16. The method of claim 15, wherein said third predetermined duration is at least 35 days.

17. The method of claim 15, wherein said third predetermined duration ranges from about 35 days to about 40 days.

18. The method of claim 15, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

19. A system for evaluating the HbA_{1c} of a patient based on BG data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

prepare the data for estimating HbA_{1c} using a predetermined sequence of mathematical formulas defined as:

pre-process the data,

estimate HbA_{1c} using at least one of four predetermined formulas, and

validate the estimate via sample selection criteria.

20. The system of claim 19, wherein said first predetermined duration is about 60 days.

21. The system of claim 19, wherein said first predetermined duration ranges from about 45 days to about 75 days.

22. The system of claim 19, wherein said first predetermined duration ranges

from about 45 days to about 90 days.

23. The system of claim 19, wherein the preprocessing of the data for each patient comprise:

conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

24. The system of claim 19, wherein the preprocessing of the data for each patient using predetermined mathematical formulas defined as:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l) via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(\text{Scale})^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals ,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

25. The system of claim 24, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

26. The system of claim 24, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,
if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,
if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and
if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

27. The system of claim 26, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,
E1 = 0.50567*BGMM1+0.074*L06+2.69,
E2 = 0.55555*BGMM1-0.074*L06+2.96,
E3 = 0.44000*BGMM1+0.035*L06+3.65; and
if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

28. The system of claim 27, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,
if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,
if (RLO1 is ≤about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and
if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

29. The system of claim 28 for estimating the HbA_{1c} of a patient based on BG

data collected over the first predetermined duration, said system comprising:

estimating HbA_{1c} using at least one of four predetermined mathematical formulas defined as:

a) HbA1c = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 6.

RLO1 is the Low BG Index of claim 6.

RHI1 is the High BG Index of claim 6; or

c) HbA1c = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA1c reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 6; or

d) HbA1c = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 6.

30. The system of claim 29, wherein said second predetermined duration is about three months.

31. The system of claim 29, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

32. The system of claim 29, wherein said second predetermined duration ranges from about 2.5 months to six months.

33. The system of claim 29, wherein the validation of the HbA1c estimate using sample selection criteria of HbA1c estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA1c estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 6

RHI1 is the High BG Index of claim 6; or

d) a randomness of data criterion-2 wherein HbA1c estimate is validated or displayed only if the ratio (NO6 >= about 3%).

wherein

N06 is the percentage of readings during the night of claim 6

34. The system of claim 33, wherein said third predetermined duration is at least 35 days.

35. The system of claim 33, wherein said third predetermined duration ranges from about 35 days to about 40 days.

36. The system of claim 33, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

37. A system for evaluating the HbA_{1c} of a patient based on BG data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

prepare the data for estimating HbA_{1c} using a predetermined sequence of mathematical formulas defined as:

pre-process the data;

estimate HbA_{1c} using at least one of four predetermined formulas; and

validate the estimate via sample selection criteria.

38. A computer program product comprising a computer useable medium having computer program logic for enabling at least one processor in a computer system to evaluate the HbA_{1c} of a patient based on BG data collected over a first predetermined duration, said computer program logic comprising:

preparing the data for estimating HbA_{1c} using a predetermined sequence of mathematical formulas defined as:

pre-processing of the data,

estimating HbA_{1c} using at least one of four predetermined formulas, and

validation of the estimate via sample selection criteria.

39. The computer program product of claim 38, wherein said computer program logic further comprises the steps of claim 11.

40. A method for evaluating the long term probability for severe hypoglycemia (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data collected over a predetermined duration, said method comprising:

computing LBGI based on said collected BG data; and

estimating the number of future SH episodes using a predetermined mathematical formula based on said computed LBGI.

41. The method of claim 40, wherein:

said computed LBGI is mathematically defined from a series of BG readings x_1, x_2, ... x_n taken at time points t_1, t_2, ..., t_n as:

$$LBGI = \frac{1}{n}\sum_{i=1}^{n} lbgi(x_i;2)$$

where:

$lbgi(BG;a) = 10.f(BG)^a$ if $f(BG)>0$ and 0 otherwise,

a = about 2, representing a weighting parameter.

42. The method of claim 40, further comprising:

defining predetermined risk categories(RCAT), each of said risk categories(RCAT) representing a range of values for LBGI; and

assigning said LBGI to at least one of said risk categories(RCAT).

43. The method of claim 42, wherein said risk categories(RCAT) are defined as follows:

category 1, wherein said LBGI is less than about 0.25;

category 2, wherein said LBGI is between about 0.25 and about 0.50;

category 3, wherein said LBGI is between about 0.50 and about 0.75;

category 4, wherein said LBGI is between about 0.75 and about 1.0;

category 5, wherein said LBGI is between about 1.0 and about 1.25;

category 6, wherein said LBGI is between about 1.25 and about 1.50;

category 7, wherein said LBGI is between about 1.5 and about 1.75;

category 8, wherein said LBGI is between about 1.75 and about 2.0;

category 9, wherein said LBGI is between about 2.0 and about 2.5;

category 10, wherein said LBGI is between about 2.5 and about 3.0

category 11, wherein said LBGI is between about 3.0 and about 3.5;

category 12, wherein said LBGI is between about 3.5 and about 4.25;

category 13, wherein said LBGI is between about 4.25 and about 5.0;

category 14, wherein said LBGI is between about 5.0 and about 6.5; and

category 15, wherein said LBGI is above about 6.5.

44. The method of claim 42, further comprising:

defining a probability of incurring a select number of SH episodes respectively for each of said assigned risk categories(RCAT).

45. The method of claim 42, further comprising:

defining a probability of incurring a select number of SH episodes within a next first predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - exp(-a.x^b)$ for any $x>0$ and 0 otherwise, wherein:

a = about -4.19

b = about 1.75

46. The method of claim 45, wherein said first predetermined duration is about one month.

47. The method of claim 45, wherein said first predetermined duration ranges from about 0.5 months to about 1.5 months.

48. The method of claim 45, wherein said first predetermined duration ranges from about 0.5 months to about 3 months.

49. The method of claim 42, further comprising:

defining a probability of incurring a select number of SH episodes within a next second predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - exp(-a.x^b)$ for any $x>0$ and 0 otherwise, wherein:

a = about -3.28

b = about 1.50

50. The method of claim 49, wherein said second predetermined duration is about three months.

51. The method of claim 49, wherein said second predetermined duration ranges from about 2 months to about 4 months.

52. The method of claim 49, wherein said second predetermined duration ranges from about 3 months to about 6 months.

53. The method of claim 42, further comprising:

defining a probability of incurring a select number of SH episodes within the next third predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - exp(-a.x^b)$ for any $x>0$ and 0 otherwise, wherein:

a = about -3.06

b = about 1.45.

54. The method of claim 53, wherein said third predetermined duration is about 6 months.

55. The method of claim 53, wherein said third predetermined duration ranges from about 5 months to about 7 months.

56. The method of claim 53, wherein said third predetermined duration ranges from about 3 months to about 9 months.

57. The method of claim 42, further comprising:

defining a probability of incurring a select number of MH episodes within the next month respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - exp(-a.x^b)$ for any $x>0$ and 0 otherwise, wherein:

a = about -1.58

b = about 1.05.

58. The method of claim 42, further comprising:

defining a probability of incurring a select number of MH episodes within the next 3 months respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - exp(-a.x^b)$ for any $x>0$ and 0 otherwise, wherein:

a = about -1.37

b = about 1.14.

59. The method of claim 42, further comprising:

defining a probability of incurring a select number of MH episodes within the next 6 months respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - exp(-a.x^b)$ for any $x>0$ and 0 otherwise, wherein:

a = about -1.37

b = about 1.35.

60. The method of claim 40, further comprising:

assigning classifications of risk for future significant hypoglycemia of the patient.

61. The method of claim 60, wherein said classifications are defined as follows:

minimal risk, wherein said LBGI is less than about 1.25;

low risk, wherein said LBGI is between about 1.25 and about 2.50;

moderate risk, wherein said LBGI is between about 2.5 and about 5; and

high risk, wherein said LBGI is above about 5.0.

62. A system for evaluating the long term probability for severe hypoglycemia (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data collected over a predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

compute LBGI based on said collected BG data, and

estimate the number of future SH episodes using a predetermined mathematical formula based on said computed LBGI.

63. The method of claim 62, wherein:

said computed LBGI is mathematically defined from a series of BG readings x_1, x_2, ... x_n taken at time points t_1, t_2, ..., t_n as:

$$LBGI = \frac{1}{n}\sum_{i=1}^{n} lbgi(x_i;2)$$

where:

$lbgi(BG;a) = 10.f(BG)^a$ if $f(BG)>0$ and 0 otherwise,

a = about 2, representing a weighting parameter.

64. The system of claim 62, further comprising:

defining predetermined risk categories(RCAT), each of said risk categories(RCAT) representing a range of values for LBGI; and

assigning said LBGI to at least one of said risk categories(RCAT).

65. The system of claim 64, wherein said risk categories (RCAT) are defined as follows:

category 1, wherein said LBGI is less than about 0.25;

category 2, wherein said LBGI is between about 0.25 and about 0.50;

category 3, wherein said LBGI is between about 0.50 and about 0.75;

category 4, wherein said LBGI is between about 0.75 and about 1.0;

category 5, wherein said LBGI is between about 1.0 and about 1.25;

category 6, wherein said LBGI is between about 1.25 and about 1.50;

category 7, wherein said LBGI is between about 1.5 and about 1.75;

category 8, wherein said LBGI is between about 1.75 and about 2.0;
category 9, wherein said LBGI is between about 2.0 and about 2.5;
category 10, wherein said LBGI is between about 2.5 and about 3.0
category 11, wherein said LBGI is between about 3.0 and about 3.5;
category 12, wherein said LBGI is between about 3.5 and about 4.25;
category 13, wherein said LBGI is between about 4.25 and about 5.0;
category 14, wherein said LBGI is between about 5.0 and about 6.5; and
category 15, wherein said LBGI is above about 6.5.

66. The system of claim 64, further comprising:
defining a probability of incurring a select number of SH episodes respectively for each of said assigned risk categories (RCAT).

67. The system of claim 64, further comprising:
defining a probability of incurring a select number of SH episodes within a next first predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - exp(-a.x^b)$ for any $x>0$ and 0 otherwise, wherein:
a = about -4.19
b = about 1.75.

68. The system of claim 67, wherein said first predetermined duration is about one month.

69. The system of claim 67, wherein said first predetermined duration ranges from about 0.5 months to about 1.5 months.

70. The system of claim 67, wherein said first predetermined duration ranges from about 0.5 months to about 3 months.

71. The system of claim 64, further comprising:

defining a probability of incurring a select number of SH episodes within a next second predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - exp(-a.x^b)$ for any $x>0$ and 0 otherwise, wherein:

a = about -3.28

b = about 1.50.

72. The system of claim 71, wherein said second predetermined duration is about three months.

73. The system of claim 71, wherein said second predetermined duration ranges from about 2 months to about 4 months.

74. The system of claim 71, wherein said second predetermined duration ranges from about 3 months to about 6 months.

75. The system of claim 64, further comprising:

defining a probability of incurring a select number of SH episodes within the next third predetermined duration respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - exp(-a.x^b)$ for any $x>0$ and 0 otherwise, wherein:

a = about -3.06

b = about 1.45.

76. The system of claim 75, wherein said third predetermined duration is about 6 months.

77. The system of claim 75, wherein said third predetermined duration ranges from about 5 months to about 7 months.

78. The system of claim 75, wherein said third predetermined duration ranges from about 3 months to about 9 months.

79. The system of claim 64, further comprising:

defining a probability of incurring a select number of MH episodes within the next month respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - exp(-a.x^b)$ for any $x>0$ and 0 otherwise, wherein:

a = about -1.58

b = about 1.05.

80. The system of claim 64, further comprising:

defining a probability of incurring a select number of MH episodes within the next 3 months respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - exp(-a.x^b)$ for any $x>0$ and 0 otherwise, wherein:

a = about -1.37

b = about 1.14.

81. The system of claim 64, further comprising:

defining a probability of incurring a select number of MH episodes within the next 6 months respectively for each of said assigned risk categories(RCAT), using the formula:

$F(x) = 1 - exp(-a.x^b)$ for any $x>0$ and 0 otherwise, wherein:

a = about -1.37

b = about 1.35.

82. The system of claim 62, further comprising:

assigning classifications of risk for future significant hypoglycemia of the patient.

83. The system of claim 82, wherein said classifications are defined as

follows:

minimal risk, wherein said LBGI is less than about 1.25;

low risk, wherein said LBGI is between about 1.25 and about 2.50;

moderate risk, wherein said LBGI is between about 2.5 and about 5; and

high risk, wherein said LBGI is above about 5.0.

84. A system for evaluating the long term probability for severe hypoglycemia (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data collected over a predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

compute LBGI based on said collected BG data, and

estimate the number of future SH episodes using a predetermined mathematical formula based on said computed LBGI.

85. A computer program product comprising a computer useable medium having computer program logic for enabling at least one processor in a computer system to evaluate the long term probability for severe hypoglycemia (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data collected over a predetermined duration, said computer program logic comprising:

computing LBGI based on said collected BG data; and

estimating the number of future SH episodes using a predetermined mathematical formula based on said computed LBGI.

86. The computer program product of claim 85, wherein said computer program logic further comprises the steps of claim 42.

87. A method for evaluating the short term probability for severe hypoglycemia (SH) of a patient based on BG data collected over a predetermined duration, said method comprising:

computing scale values based on said collected BG data; and

computing the low BG risk value (RLO) for each BG data.

88. The method of claim 87, wherein:

said computed RLO(BG) is mathematically defined as:

Scale = $[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl

Risk = $22.765(\text{Scale})^2$

if (BG is less than about 112.5) then:

RLO(BG) = Risk, otherwise

RLO(BG) = 0.

89. The method of claim 87, wherein:

said computed RLO(BG) is mathematically defined as:

Scale=$[\ln(BG)]^{1.026} - 1.861$, wherein BG is measured in units of mmol/l

Risk = $32.184(\text{Scale})^2$

if (BG is ≤about 112.5) then:

RLO(BG) = Risk, otherwise

RLO(BG) = 0.

90. The method of claim 87, wherein:

computing LBGI based on said collected BG data, said computed LBGI is mathematically defined from a series of BG readings $x_1, x_2, \ldots x_n$ taken at time points $t_1, t_2, \ldots, t_n$ as:

$$LBGI = \frac{1}{n}\sum_{i=1}^{n} lbgi(x_i;2)$$

where:

$lbgi(BG;a)$ = RLO(BG).

91. The method of claim 87, wherein:

computing provisional LBGI based on said collected BG data, said computed provisional LBGI is mathematically defined from mathematically defined as:

$LBGI(1) = RLO(x_1)$

$RLO2(1) = 0$

$LBGI(j) = ((j-1)/j) * LBGI(j-1) + (1/j) * RLO(x_j)$

$RLO2(j) = ((j-1)/j) * RLO2(j-1) + (1/j) * (RLO(x_j) - LBGI(j))^2$.

92. The method of claim 91, wherein:

computing SBGI, said computed SBGI is mathematically defined as:

$SBGI(n) = \sqrt{(RLO2(n))}$.

93. The method of claim 92, comprising qualifying or providing a warning of upcoming short term SH wherein if:

(LBGI(150) ≥2.5 and LBGI(50) ≥ (1.5*LBGI(150) and SBGI(50) ≥ SBGI(150)) then said issue of warning is qualified or provided, or

RLO ≥(LBGI(150)+1.5*SBGI(150)) then said issue of warning is qualified or provided;

otherwise:

a warning is not necessarily qualified or provided.

94. The method of claim 92, comprising qualifying or providing a warning of upcoming short term SH wherein if:

(LBGI(n) ≥α and SBGI(n) ge (β)) then said issue of warning is qualified or provided, and/or

(RLO(n) ≥(LBGI(n)+ γ * SBGI(n))) then said issue of warning is qualified or provided;

otherwise:

a warning is not necessarily qualified or provided, wherein α, β, and γ are

threshold parameters.

95. The method of claim 94, wherein said threshold parameters α, β, and γ are defined as α = about 5, β = about 7.5, γ = about 1.5.

96. The method of claim 94, wherein said threshold parameters α, β, and γ are defined as any combination in a, b, and/or c, or as any intermediate combination of values of said parameters between the values of said parameters in a, b, and/or c below:

a) $\alpha = 6.4$, $\beta = 8.2$, $\gamma = 1.5$, $\alpha = 5.0$, $\beta = 7.5$, $\gamma = 1.3$;

b) $\alpha = 6.0$, $\beta = 7.5$, $\gamma = 1.5$, $\alpha = 4.9$, $\beta = 7.0$, $\gamma = 1.2$; and/or

c) $\alpha = 5.5$, $\beta = 7.5$, $\gamma = 1.5$, $\alpha = 4.8$, $\beta = 7.0$, $\gamma = 1.2$.

97. The method of claim 94, wherein said threshold parameters α, β, and γ are defined as any combination in a, b, and/or c, or as any intermediate combination of values of said parameters between the values of said parameters in a, b, and/or c below:

a). α about 6.4, β about 8.2, γ about 1.5, α about 5.0, β about 7.5, γ about 1.3;

b). α about 6.0, β about 7.5, γ about 1.5, α about 4.9, β about 7.0, γ about 1.2; and/or

c). α about 5.5, β about 7.5, γ about 1.5, α about 48, β about 7.0, γ about 1.2.

98. A system for evaluating the short term probability for severe hypoglycemia (SH) of a patient based on BG data collected over a predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

compute scale values based on said collected BG data; and

compute the low BG risk value (RLO) for each BG data.

99. The system of claim 98, wherein:

said computed RLO(BG) is mathematically defined as:

Scale = $[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl

Risk = $22.765(\text{Scale})^2$

if (BG is less than about 112.5) then:

RLO(BG) = Risk, otherwise

RLO(BG) = 0.

100. The system of claim 98, wherein:

said computed RLO(BG) is mathematically defined as:

Scale=$[\ln(BG)]^{1.026} - 1.861$, wherein BG is measured in units of mmol/l

Risk = $32.184(\text{Scale})^2$

if (BG is $\leq$about 112.5) then:

RLO(BG) = Risk, otherwise

RLO(BG) = 0.

101. The system of claim 98, wherein:

computing LBGI based on said collected BG data, said computed LBGI is mathematically defined from a series of BG readings $x_1, x_2, \ldots x_n$ taken at time points $t_1, t_2, \ldots, t_n$ as:

$$LBGI = \frac{1}{n}\sum_{i=1}^{n} lbgi(x_i;2)$$

where:

$lbgi(BG;a)$ = RLO(BG).

102. The system of claim 98, wherein:

computing provisional LBGI based on said collected BG data, said computed provisional LBGI is mathematically defined from mathematically defined as:

LBGI(1) = RLO(x_1)

RLO2(1) = 0

LBGI(j)= ((j-1)/j) * LBGI (j-1) + (1/j) * RLO(x_j)

RLO2(j)=((j-1)/j)*RLO2(j-1) + (1/j)*(RLO(x_j)-LBGI(j))^2.

103. The system of claim 102, wherein:

computing SBGI, said computed SBGI is mathematically defined as:

SBGI(n)= $\sqrt{(RLO2(n))}$.

104. The system of claim 103, comprising qualifying or providing a warning of upcoming short term SH wherein if:

(LBGI(150) ≥2.5 and LBGI(50) ≥ (1.5*LBGI(150) and SBGI(50) ≥ SBGI(150)) then said issue of warning is qualified or provided, or

RLO ≥(LBGI(150)+1.5*SBGI(150)) then said issue of warning is qualified or provided;

otherwise:

a warning is not necessarily qualified or provided.

105. The system of claim 103, comprising qualifying or providing a warning of upcoming short term SH wherein if:

(LBGI(n) ≥α and SBGI(n) ge (β)) then said issue of warning is qualified or provided, and/or

(RLO(n) ≥(LBGI(n)+ γ * SBGI(n))) then said issue of warning is qualified or provided;

otherwise:

a warning is not necessarily qualified or provided, wherein α, β, and γ are threshold parameters.

106. The system of claim 105, wherein said threshold parameters α, β, and γ are defined as α = about 5, β = about 7.5, γ = about 1.5.

107. The system of claim 105, wherein said threshold parameters α, β, and γ are defined as any combination in a, b, and/or c, or as any intermediate combination of values of said parameters between the values of said parameters in a, b, and/or c below:

a) $\alpha = 6.4$, $\beta = 8.2$, $\gamma = 1.5$, $\alpha = 5.0$, $\beta = 7.5$, $\gamma = 1.3$;

b) $\alpha = 6.0$, $\beta = 7.5$, $\gamma = 1.5$, $\alpha = 4.9$, $\beta = 7.0$, $\gamma = 1.2$; and/or

c) $\alpha = 5.5$, $\beta = 7.5$, $\gamma = 1.5$, $\alpha = 4.8$, $\beta = 7.0$, $\gamma = 1.2$.

108. The system of claim 105, wherein said threshold parameters α, β, and γ are defined as any combination in a, b, and/or c, or as any intermediate combination of values of said parameters between the values of said parameters in a, b, and/or c below:

a). α about 6.4, β about 8.2, γ about 1.5, α about 5.0, β about 7.5, γ about 1.3;

b). α about 6.0, β about 7.5, γ about 1.5, α about 4.9, β about 7.0, γ about 1.2; and/or

c). α about 5.5, β about 7.5, γ about 1.5, α about 48, β about 7.0, γ about 1.2.

109. A system for evaluating the short term probability for severe hypoglycemia (SH) of a patient based on BG data collected over a predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

compute scale values based on said collected BG data; and

compute the low BG risk value (RLO) for each BG data.

110. A computer program product comprising a computer useable medium having computer program logic for enabling at least one processor in a computer system to evaluating the short term probability for severe hypoglycemia (SH) of a patient based on BG data collected over a predetermined duration, said computer program logic

comprising:

computing scale values based on said collected BG data; and

computing the low BG risk value (RLO) for each BG data.

111. The computer program product of claim 110, wherein said computer program logic further comprises the steps of claim 92.